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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,731	04/05/2001	Jerome Owen Cantor		8515

7590
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01/02/2002

EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
1651	6

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/826,731	CANTOR ET AL.
	Examiner	Art Unit
	Michael V. Meller	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 December 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

The Inventor's or the Assignee's signature is present on the attached application has been received.

Attachments

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2

- 4) Drawing Outlines (PTO-1449) Paper No(s) _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of pneumonia as the disorder to be treated is noted.

The election of species is still deemed to be proper and is thus made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing since it is not clear who the subject of the "treating" is. It would be clearer if applicant inserted "of a patient" after, "lung" in the claim. Instead of stating "this protein" it would be clearer if applicant stated, "said lysozyme" for proper antecedent basis. Further, it would be clearer if applicant ended the claim with "to said patient" to make the claim more definite as a process claim with a definite step.

The use of "such as" in the claims is confusing. If applicant wants to further limit

the claim, applicant is asked to write a dependent claim doing so.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 13, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavrilenko et al.

The abstract teaches that lysozyme is administered intratracheally to patients ages over 60 to under 30. The lysozyme is administered both with and without carbenicillin.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kats et al.

Kats teaches that lysozyme is administered by spraying it into the pharynx and larynx. It also teaches that it is derived from eggs.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhorov et al.

The reference teaches that lysozyme is administered to patients by aerosol administration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyrenkov et al. taken with Gavrilenko et al., Zhorov et al. and Kats et al.

Vyrenkov teaches that patients with pneumonia were given lysozyme.

The reference does not teach that the lysozyme was administered intratracheally, nebulized, that the lysozyme comes from eggs, or produced by fermentation, that it is given to a human neonate or that it is given in the specific amount in claim 16.

The teachings of the other references are above.

It would have been obvious to one of skill in the art to administer the lysozyme intratracheally since the other references establish that this is preferred way to administer the lysozyme to a patient. Further, since one wants to treat pneumonia one would administer it by nebulization. To derive the enzyme from eggs is known as evidenced by the references and if one gets the enzyme from fermentation is also obvious since microorganisms routinely produce lysozyme. It is simply the choice of the artisan in an effort to optimize the results to use these different sources of the enzyme or administration of the enzyme. The same is true if the enzyme is given to a human neonate or in the claimed amount. To give the enzyme to a human neonate is simply

Contract it more thus one would want to administer the enzyme in a smaller amount. In fact, there

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lysozyme at the claimed amounts is also obvious since the amount used is simply the choice of the artisan in an effort to optimize the claimed results. Further, the range 10 µg to 1 mg is a very broad range for such administration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller
Examiner
Art Unit 1651

MVM
December 29, 2001